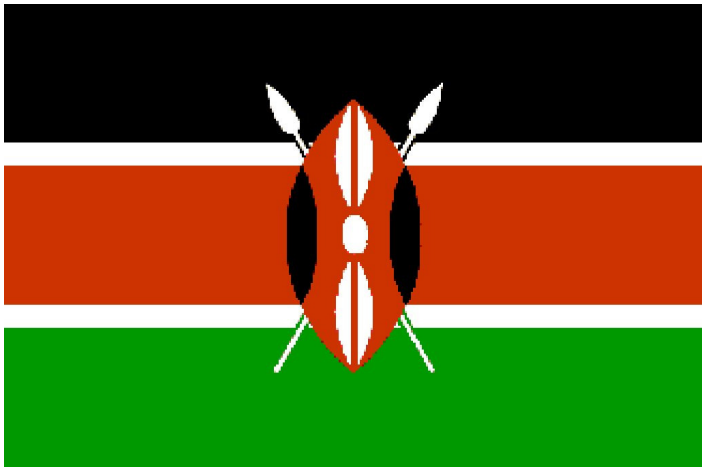
KENYA



PHARMACEUTICAL COUNTRY PROFILE

Kenya Pharmaceutical Country Profile

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Foreword

This Pharmaceutical Country Profile for Kenya (2010) has been developed by the Ministry of Medical Services with support of the World Health Organization. The Profile contains information on existing socio-economic and health-related conditions, resources, regulatory structures and processes and outcomes relating to the pharmaceutical sector in Kenya. The information is intended for use in health policy making and strategic planning; and it is part of ongoing efforts to integrate pharmaceuticals within the national health policy and strategic framework.

Because pharmaceuticals are cross-cutting and multi-faceted, appropriate pharmaceutical policies require analysis and monitoring of a wide range of data from multiple sources. This Profile is the first compilation of such data for Kenya, and it provides a much-needed reference for Government, health development and implementing partners as well as other health stakeholders. All efforts have been made to compile data that is nationally representative and up to date, by drawing from international sources (e.g. the World Health Statistics[i]), as well as from national and institutional surveys and databases. The data sources for each piece of information are annexed as tables the end of this document.

We gratefully acknowledge the efforts of the national team which compiled this Profile and, in particular, the technical support from WHO, which enabled adaptation of the tools, data compilation and development of the Profile.

It is my hope that this Profile will serve as a useful tool for the health sector stakeholders, researchers and all those interested in the pharmaceutical sector in Kenya. We welcome comments or feedback on the use of this Profile and any suggestions on its improvement.

Dr Francis Kimani
Director of Medical Services

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List of Abbreviations

GDP	Gross Domestic Product
GJLOS	Governance, Justice, Law and Order Sector
GNI	Gross National Income
GSPOA	Global Strategy and Plan of Action
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
HAI-A	Health Action International - Africa
HIS	Health Information System
MRA	Medicines Regulatory Authority
NCU	National Currency Units
NHA	National Health Accounts
NHIF	National Health Insurance Fund
PPB	Pharmacy and Poisons Board
TRIPS	Trade-Related Aspects of Intellectual Property
WHO	World Health Organization
WHS	World Health Statistics

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Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Kenya. The aim of this document is to compile all relevant, existing information on the pharmaceuticals sector and make it available to the public in a user-friendly format. This document forms part of the WHO Pharmaceutical Country Profiles project, which was piloted in 13 countries in 2010 (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization plans to support all WHO Member States to develop similar country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Regulation, (5) Medicines Financing, (6) Supply of Pharmaceuticals, (7) Rational Use of Medicines, and (8) Household Surveys. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based only on data derived from these core indicators; while the tables in the annexes present all data collected for each of the indicators, both core and supplementary. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO) as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries. Data collection in the pilot countries was conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not

to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information available at the central level. To facilitate the work of the national teams, the questionnaires were pre-filled using all data available at WHO HQ before being sent out to countries. A coordinator was nominated for each of the 13 pilot countries. The coordinator for Kenya was Dr Regina Mbindyo of the WHO Country Office in Kenya.

The completed questionnaires were then used to produce individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO web site.

This profile will be regularly updated by the Ministry of Medical Services with the support of WHO. Comments, suggestions or corrections may be sent to:

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Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Kenya.

1.1 Demographics and Socioeconomic Indicators

The total population of Kenya in 2008 was 38,765,000 with an annual population growth rate of 2.6%. The annual GDP growth rate is 3.6%. The GNI per capita is US$ 1,580 [1] [2].

1.2 Mortality and Causes of Death

The life expectancy at birth for men is 53 years and for women is 55 years [1]. The infant mortality rate is 52/1,000 live births. For children under the age of 5, the mortality rate is 74/1,000 live births. The maternal mortality rate is 488/100,000 live births [3].

The top 10 diseases causing outpatient morbidity in Kenya are [4]:

1. Malaria
2. Diseases of the respiratory system
3. Diseases of the skin
4. Diarrhoeal diseases
5. Intestinal worm infestation
6. Accidents
7. Pneumonia
8. Eye infections
9. Rheumatism
10. Urinary tract infections

Section 2 - Health Services

This section provides information regarding health expenditure and human resources in Kenya. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

2.1 Health Expenditures

In Kenya, the total annual expenditure on health (THE) in 2008 was KES 107,498 million (Kenya Shillings) (US$ 1,502 million). The total health expenditure is 4.5 % of the GDP. The total annual expenditure on health per capita was KES 2,864 (US$ 40).

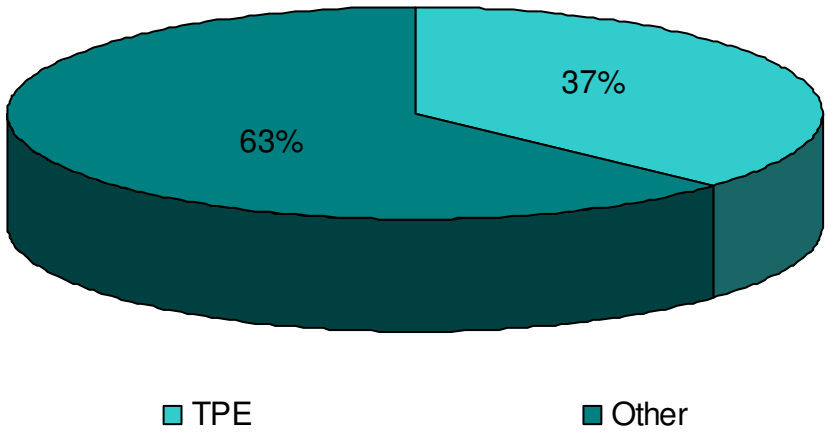
Government[1] annual expenditure on health (GGHE) accounts for 37.4% of the total expenditure on health, with a government per capita expenditure on health of KES 1,072 (US$ 15). The government annual expenditure on health represents 7.1% of the total government budget; private health expenditure covers the remaining 62.6% of total health expenditure [5].

Of the total population, 22 % is covered by a public health service or public health insurance/social insurance or other sickness funds, while 0.9 % is covered by private health insurance schemes [6].

Total pharmaceutical expenditure (TPE) in Kenya in 2006 was KES 26,796 million (US$ 372 million), which represents a per capita pharmaceutical expenditure of KES 714 (US$ 9.9). Total pharmaceutical expenditure accounts for 1.65 % of GDP and makes up 36.64 % of the total health expenditure (Figure 1).
Government expenditure on pharmaceuticals represents 9.03 % of the total expenditure on pharmaceuticals (Figure 2). The government expenditure on pharmaceuticals per capita in 2006 was KES 66.19 (US$ 0.92). Private expenditure on pharmaceuticals in 2006 was KES 10,340 million (US$ 143 million) [5].

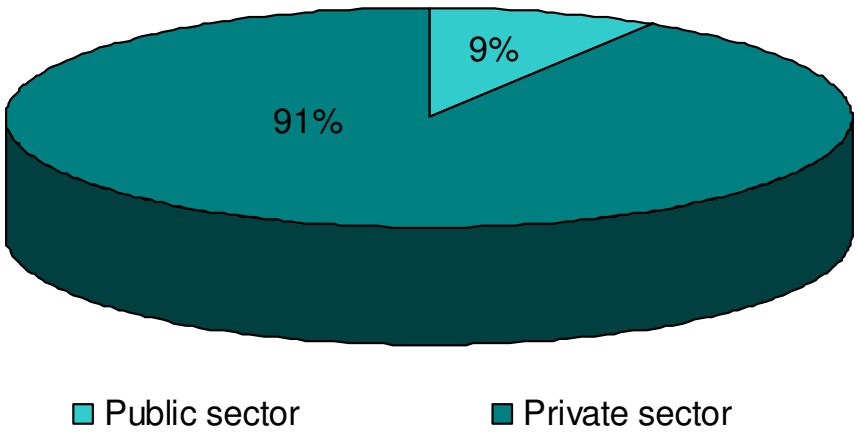
[1] By government expenditure it is meant all expenditure from public sources, like central government, local government, insurance funds and parastatal companies. This follows the WHO NHA definition.

FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure in 2006



Source: NHA, 2006

FIGURE 2: Share of public and private sector to Total Pharmaceutical Expenditure in 2006



Source: NHA, 2006

2.2 Health Personnel

The status of the health workforce is summarized in the table below and in Figures 3 and 4.

Human Resource	
Licensed pharmacists (all sectors)	0.51/10,000 [7]
Pharmacists in the public sector	0.15/10,000 [8]
Pharmaceutical technicians and assistants (all sectors)	0.38/10,000 [7]
Physicians (all sectors)	1.36/10,000
Nursing and midwifery personnel (all sectors)	11.2/10,000 [1]

Figure 3: Population coverage of the Health Workforce in Kenya (all sectors)

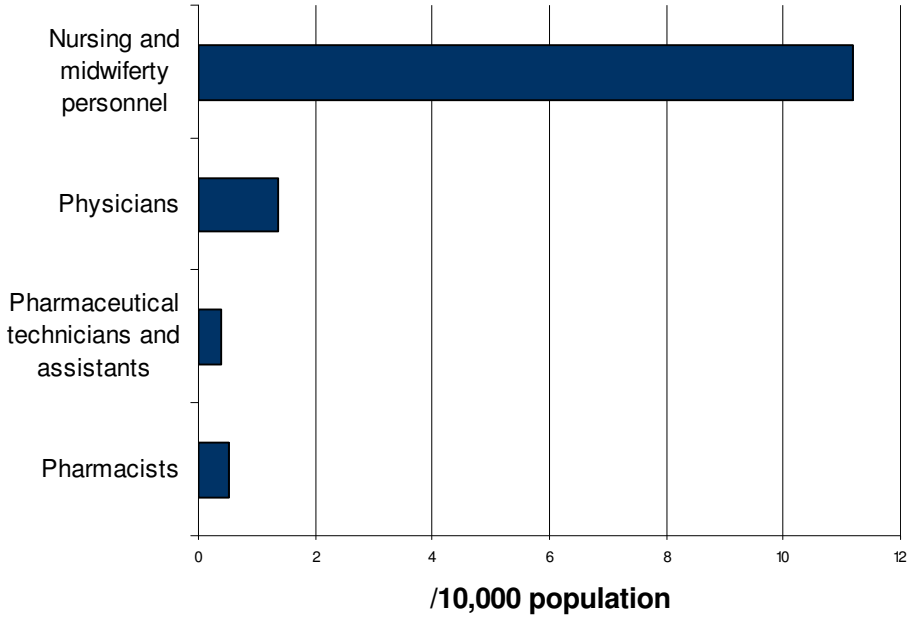
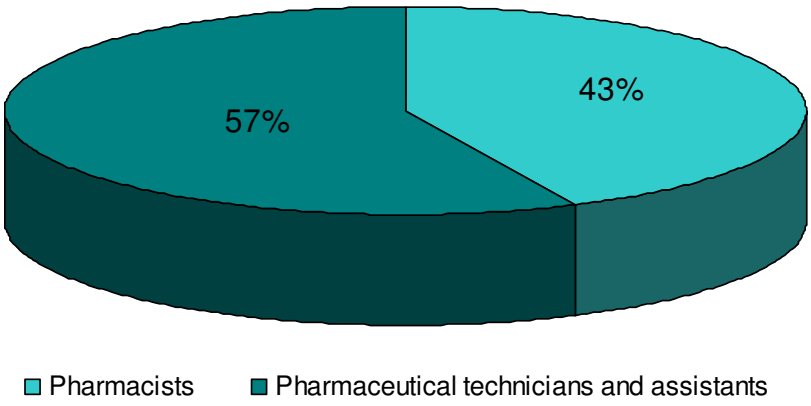


Figure 4: Distribution of Pharmaceutical Personnel in 2004



Source: Global Health Atlas, 2004

A strategic plan for pharmaceutical human resource development has not yet been developed in Kenya.

2.3 Health Infrastructure

Some key statistics on the coverage of health infrastructure (hospitals and primary health facilities) are described in the table below.

Infrastructure	
Hospitals	0.12/10,000
Hospital beds	12.8/10,000
Primary health care units and centres	0.99/10,000 [4]
Licensed pharmacies	Unknown

Section 3 - Policy Issues

This section addresses the main structure of the pharmaceutical policy in Kenya, as well as information about the capacity for pharmaceutical manufacturing and regulations regarding patents.

3.1 Policy Framework

The Kenya Health Policy Framework (KHPF) is the National Health Policy (NHP). It was developed in 1994 [9] and is currently under review. The Kenya National Pharmaceutical Policy (KNPP) is the official National Medicines Policy document. It was updated in 2010.

The KNPP covers:

Aspect of policy	Covered
Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	Yes
Medicines procurement	Yes
Medicines distribution	Yes
Medicines regulation	Yes
Pharmacovigilance	Yes
Rational use of medicines	Yes
Human resource development	Yes
Research	Yes
Monitoring and evaluation	Yes
Traditional Medicine	Yes

[10]

** As part of the mandate of the MRA*

A National Pharmaceutical Strategy is under development as the official NMP implementation plan [11]. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in both the constitution and the NMP [12]. There are official written guidelines on medicines donations [13].

Implementation of the pharmaceutical policy is regularly monitored within the context of national joint health sector planning and monitoring and evaluation (M&E). The Department of Pharmacy, Division of Pharmaceutical Policies, is responsible for pharmaceutical policy monitoring [14].

There is a multisectoral national good governance policy in Kenya. The Ministry of Justice, National Cohesion and Constitutional Affairs coordinates the GJLOS (Governance, Justice, Law and Order Sector), which is responsible for the good governance policy [10] [15]. Good governance for the pharmaceutical sector is enshrined as a principle of the KNPP.

There is a formal code of conduct for public officials [16], but there is no specific policy in place to manage and sanction conflict of interest issues in pharmaceutical affairs. A whistle-blowing mechanism exists, which allows individuals to raise concerns about wrongdoing occurring in the public sector, including the pharmaceutical sector [17].

3.2 Intellectual Property Laws and Medicines

Kenya is a member of the World Trade Organization, and, being a developing country, it is not eligible for the transitional period to 2016. The Intellectual Property Act is the national patent law, and it contains the following (TRIPS) flexibilities and safeguards, in line with the TRIPS Agreement:

Flexibility and safeguards	Included
Compulsory licensing provisions that can be applied for reasons of public health	Yes
Bolar exceptions[2]	Yes
Parallel importing provisions	Yes

[2] Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully. In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article [In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]*

The country is engaged in initiatives to strengthen capacity, manage and apply intellectual property rights, contribute to innovation and promote public health. There are legal provisions for data exclusivity for pharmaceuticals. There national legislation has no provisions for patent extension or linkage between patent status and marketing authorization [18].

3.3 Manufacturing

There are 45 licensed pharmaceutical manufacturers in Kenya. Kenya has capacity for:

Manufacturing capabilities	
Research and Development for discovering new active substances	No
Production of pharmaceutical starting materials (APIs)	No
The production of formulations from pharmaceutical starting material	Yes
The repackaging of finished dosage forms	Yes

In 2010, the percentage market share (by value) of pharmaceuticals produced by domestic manufacturers was 28 % [10] [19] [20].

Section 4 - Regulation

This section covers a broad range of pharmaceutical regulatory policy, institutions and practices in Kenya

4.1 Regulatory Framework

In Kenya, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA), which is the Pharmacy and Poisons Board (PPB). The PPB operates as a department of the Ministry of Health, but there are initiatives to establish it as a semi-autonomous agency under the MoH [21]. The MRA has its own website and the URL address is http://www.pharmacyboardkenya.org. The MRA is involved in harmonization/collaboration initiatives, which include the African Medicines Regulatory Harmonization and the Harmonization of Medicines Registration in the EAC. An assessment of the medicines regulatory system was conducted in 2006 by WHO [20] [22].

4.2 Marketing Authorization

In Kenya, legal provisions require that all pharmaceutical products on the market receive marketing authorization (registration). Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. The number of pharmaceutical products registered in Kenya in 2010 was 13,000. There are no legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available regularly. Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN. The MRA charges a fee for Medicines Market Authorization (registration) based on applications [20] [23] [24] [25].

4.3 Regulatory Inspection

In Kenya, legal provisions exist allowing for the appointment of government pharmaceutical inspectors [21]. The Regulatory Authority has 43 inspectors. There are legal provisions permitting inspectors to inspect premises where pharmaceutical activities are performed – these provisions require inspections to be performed. Inspection is a pre-

requisite for licensing facilities and the requirements are the same for both public and private facilities [20].

4.4 Import Control

Legal provisions requiring authorization to import medicines exist. Laws exist that allow the sampling of imported products for testing. Legal provisions requiring the importation of medicines through authorized ports of entry also exist. Regulations or laws exist to allow for inspection of imported pharmaceutical products at the authorized port of entry [21] [26].

4.5 Licensing

In Kenya, there are legal provisions requiring that manufacturers are licensed and that they comply with Good Manufacturing Practices (GMP). Guidelines on Good Manufacturing Practices have been published by the government. Legal provisions requiring importers, wholesalers, and distributers to be licensed and requiring wholesalers and distributors to comply with Good Distributing Practices exist. Guidelines for Good Distribution Practices have been published by the government.

There exist legal provisions requiring pharmacists to be registered. While private pharmacies are required to be licensed, these obligations do not extend to public pharmacies. There are government-published guidelines on Good Pharmacy Practice [20].

4.6 Market Control and Quality Control

In Kenya, there are legal provisions for controlling the pharmaceutical market and there is a national laboratory for Quality Control testing. Samples are collected by government inspectors and sent to the laboratory for post-marketing surveillance testing [20].

4.7 Medicines Advertising and Promotion

In Kenya, there are legal provisions to control the promotion and/or advertising of prescription medicines. The government is responsible for regulating promotion and/or advertising of medicines. There are legal provisions requiring the pre-approval of medicines advertisements and promotional materials; direct advertising of prescription medicines to the public is prohibited. Guidelines/Regulations exist for advertising and

promotion of non-prescription medicines. There is a national code of conduct to guide advertising and promotion of medicines undertaken by Marketing Authorization holders. Adherence to the code is compulsory and the code contains a formal process for complaints and sanctions [20] [27].

4.8 Clinical Trials

In Kenya, legal provisions requiring authorization for conducting Clinical Trials by the MRA exist. Laws require that agreement by an ethics committee or institutional review board of the Clinical Trials in order for clinical trials to be performed. Registration of the clinical trials in an international/national/regional registry is required by law. A National CT Registry is currently under development by the Pharmacy and Poisons Board [20] [28].

4.9 Controlled Medicines

Kenya is signatory to the:

- Single Convention on Narcotic Drugs, 1961
- 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961
- Convention on Psychotropic Substances 1971
- United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

There are no laws for the control of narcotic and psychotropic substances, and precursors. The annual consumption of Morphine is 0.575 mg per capita [29] [30].

4.10 Pharmacovigilance

In Kenya, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Legal provisions also exist regarding the monitoring of Adverse Drug Reactions (ADR) in Kenya, and requiring Marketing Authorization holders to continuously monitor the safety of their products and report to the MRA. A national Pharmacovigilance centre linked to the MRA exists, staffed by 3 full-time employees. The centre has not published any analysis reports in the previous two years and does not publish an ADR bulletin regularly; however

departmental reports and post-market surveillance reports are available. An official standardized form for reporting ADRs is available in Kenya. A national ADR database also exists. In the past 2 years, 23 ADR reports were sent to the database held at the WHO collaborating centre in Uppsala. ADRs are monitored in at least the following public health programs: HIV, TB, malaria and immunization [20] [21] [31] [32].

Section 5 - Medicines Financing

In this section, information is provided on the structure of user fees for medicines and on the existence of public programmes providing free medicines. Policies and regulations affecting the prices of medicines (e.g. price control and taxes) are also presented.

5.1 Medicines Coverage and Exemptions

Public programmes exist in Kenya providing free medicines to:

Patient group	Covered
Patients who cannot afford them	Yes
Children under 5	Yes
Pregnant women	Yes
Elderly persons	Yes

A public programme exists providing free medicines for:

Conditions	Covered
All diseases in the EML	No
Any non-communicable diseases	No
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes

The National Health Insurance Fund does not cover medicines for inpatients and outpatients. The Fund only provides inpatient cover for 'lodging' costs. However, the insurance benefit package is currently being expanded, to cover other inpatient costs; and an outpatient program has been initiated on a pilot basis.

Private health insurance schemes do provide medicines coverage however the coverage is currently not linked to the EML [33-36] [37].

5.2 Patients Fees and Copayments

In the health system of Kenya, at the point of delivery, there are copayments/fee requirements for consultations and medicines. For primary care facilities, level 1 and 2 patients pay a fee of KES 10 and 20 respectively (US$ 0.14 and 0.28). There are no guidelines for copayments at other levels.

Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility. Revenues are primarily used to cover facility operating costs [8].

5.3 Pricing Regulation for the Private Sector (not including the non-profit voluntary sector)

In Kenya, there are no legal or regulatory provisions affecting the pricing of medicines. The government runs an active national medicines price monitoring system for retail patient prices in the public, faith-based and private facilities. There are no regulations mandating that retail medicine price information should be publicly accessible [20] [37].

5.4 Prices, Availability and Affordability of Key Medicines

In 2004, a WHO/HAI pricing survey was conducted in Kenya the results of which are discussed below.

In the public sector, mean availability of originator medicines was 66%. The private sector had higher availability (81% for originator). For generics the availability was based on the median. In the public sector, this was 37.7 and in the private sector 72.4.

Prices of medicines have been compared to international reference prices[3] and expressed as a ratio of the international price (e.g. a price ratio of 2 would mean that the price is twice that of the international reference price). Since prices have been collected for a

[3] The International reference price is the median of prices offered by international suppliers (both for profit and not profit) as report by MHS International Price Indicator Guide (http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English). For more information on the methodology WHO/HAI pricing survey, you can download a free copy of the manual at http://apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf.

basket of medicines, the median price ratio has been selected to represent the situation in the country.

The data indicates that public procurement prices were below international reference prices: the Median Price Ratio for generics was 0.65. Public and private patient prices in Kenya are substantially greater than international reference prices - the Median Price Ratio in the public sector was 3.6 for originators and 1.99 for generics, while the private sector had higher prices (18.1 for originators and 3.33 for generics).

Affordability of medicines is measured in terms of the number of days' wages necessary to purchase treatment for a specific condition. The wage used is that for the lowest paid government worker. In the public sector of Kenya, it would take 0.2 days of wage to purchase treatment with co-trimoxazole for a child respiratory infection using generic medicines. In the private sector, medicines were just as affordable as it would also take 0.2 days of wage to purchase treatment using generic medicines (1.5 with originator) [37].

		Public procurement	Public patient	Private patient
Availability				
Mean (%)	Originator		66%	81%
	Lowest priced generic (LPG)			
Median (%)	Originator			
	Lowest priced generic (LPG)		37.7%	72.4%
Price				
Mean Price Ratio	Originator		3.6	18.1
	Lowest priced generic (LPG)	0.65	1.99	3.33
Affordability				
Number of days' wages	Originator			0.2
	Lowest priced generic (LPG)			

5.5 Duties and Taxes on Pharmaceuticals (Market)

In Kenya, there are no duties on imported active pharmaceutical ingredients, or on imported finished products. There is no value-added tax on pharmaceuticals. However, Import Declaration Fees (IDF) are levied and amount to indirect tax on pharmaceuticals. Duty and VAT are applicable to some packaging materials for pharmaceuticals, which affect the final price [8].

Section 6 - Pharmaceutical procurement and distribution in the public sector

This section provides a short overview on the system for procurement and distribution of pharmaceuticals in the public sector in Kenya.

6.1 Public Sector Procurement

Public sector procurement in Kenya is both centralized and decentralized. Centralized procurement falls under the responsibility of a semi-autonomous procurement agency, the Kenya Medical Supplies Agency (KEMSA) which is the primary public procurement agency for pharmaceutical and related products. Public sector tender bids are not made publicly available, however bid documents are available to bidders who purchase them. Details regarding public sector tender awards are publicly available. Procurements are based on prequalification of suppliers, although prequalification is only carried out where items are procured by quotation [30] [38].

6.2 Public Sector Distribution

The government pharmaceutical supply system has a Central Medical Store at the National Level and there are 8 public warehouses in the secondary tier of the public sector distribution. National guidelines on Good Distribution Practices (GDP) have been produced, but there is no licensing authority that issues GDP licenses. Hence, a list of GDP certified wholesalers and distributors in the public sector does not exist [20] [39].

6.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector of Kenya. A list of GDP-certified private sector wholesalers and distributors does not exist [20] [39].

Section 7 - Selection and rational use of medicines

This section presents the structures and policies that are in place in Kenya for the selection of essential medicines and promotion of rational drug use.

7.1 National Structures

National Standard Treatment Guidelines (STGs) for the most common illnesses are jointly produced by the two ministries in health in Kenya – the Ministry of Medical Services and the Ministry of Public Health and Sanitation. The national STGs were last updated in 2009. They cover primary, secondary and tertiary care, and paediatric conditions, among others. A National Essential Medicines List (EML) exists in Kenya and is publicly available. It was last updated in 2010 and has 359 medicines listed. A written process for selecting the medicines on the EML is undertaken. In 2008, 42 % and 39 % of public health facilities had a copy of the EML and STGs respectively.

In Kenya, there is a public national medicines information centre that provides information on medicines to prescribers, dispensers and consumers. A public education campaign on rational medicine use topics has not been conducted in the last two years. There is a national medicines and therapeutics committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines. There is no written National Strategy to contain antimicrobial resistance [40-43].

7.2 Prescribing

There are legal provisions that govern the licensing and prescribing practices of prescribers in Kenya. Legislation exists to restrict dispensing by prescribers; and regulations require hospitals to establish Drug and Therapeutics Committees (DTCs).

Prescribing by INN name is not obligatory in the public and private sector. An average of 3 medicines is prescribed per patient contact in public health facilities. Almost all (93.4%) of the medicines prescribed to outpatients in public health care facilities are on the national EML and 31.8% are prescribed by INN name. 76.7% of patients treated in public

health care facilities receive antibiotics and 13.3% receive injections. Most prescribed drugs (86%) in public health facilities are dispensed to patients in the same facility, however only 5% are adequately labelled [40] [41] [44].

7.3 Dispensing

In Kenya, there is legislation governing the dispensing practices of pharmaceutical personnel. The core pharmacist training curriculum includes components on:

Curriculum	Covered
The concept of EML	Yes
Use of STGS	Yes
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	Yes

Mandatory continuing education regarding pharmaceutical issues is not required for pharmacists.

Substitution of generic equivalents at the point of dispensing in public and private sector facilities is allowed. Both antibiotics and injectable medicines are sold over-the-counter without a prescription [20] [40].

Section 8 - Household data/access

This section provides information about household surveys held in the past in Kenya regarding actual access to medicines by normal and poor households.

In the past 5 years, a WHO/HAI Household Survey was undertaken (in 2008) to assess the status of access to medicines. Here follows some of the key findings:

In Kenya, 89% of adult patients with acute conditions took all medicines as recommended. Of adult patients with chronic conditions, 87% took all medicines as recommended [41].

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ANNEX

Data Tables

Section 1 Health and Demographic data

Indicator	Value	Year	Reference/Source
1.01 Demographic and Socioeconomic Indicators **Core Questions**			
Population, total (,000)	38,765	2008	World Health Statistics 2010
Population growth rate (Annual %)	2.6	2008	World Health Statistics 2010
GDP growth (Annual %)	3.6	2008	World Bank 2010
GNI per capita (US$ current exchange rate)	1,580	2008	World Health Statistics 2010
Supplementary questions			
Population < 15 years (% of total population)	43	2008	World Health Statistics 2010
Population > 60 years (% of total population)	4	2008	World Health Statistics 2010
Urban population (% of total population)	22	2008	World Health Statistics 2010
Fertility rate, total (Births per woman)	4.6	2008	Kenya Demographic and Health Survey 2008
Population living with less than $1/day (international PPP) (%)	19.7	2007	World Health Statistics 2010
Population living below nationally defined poverty line (%)	46.6	2006	World Bank 2010
Income share held by lowest 20% of the population (% of national income)	4.7	2005	World Bank 2010
Adult literacy rate, 15+ years (% of total population)	86.5	2008	World Bank 2010
1.02 Mortality and Causes of Death **Core questions**			
Life expectancy at birth for men (Years)	53	2008	World Health Statistics 2010
Life expectancy at birth for women (Years)	55	2008	World Health Statistics 2010
Infant mortality rate, between birth and age 1 (/1,000 live births)	52	2008	KDHS 2009-09
Under 5 mortality rate	74	2008	KDHS 2009-09

(/1,000 live births)			
Maternal mortality ratio (/100,000 live births)	488	2008	KDHS 2009-09
List of top 10 diseases causing morbidity	1. Malaria 2. Diseases of the Respiratory System 3. Diseases of the skin 4. Diarrhoeal diseases 5. Intestinal worm infestation 6. Accidents 7. Pneumonia 8. Eye infections 9. Rheumatism 10. Urinary tract infections	2008	HIS, July 2009
Comments	The listed top 10 diseases causing morbidity refer to national major causes of outpatient morbidity		

Supplementary questions			
Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	371	2008	World Health Statistics 2010
Neonatal mortality rate (/1,000 live births)	31	2008	KDHS 2009-09
Age-standardized mortality rate by non-communicable diseases (/100,000 population)	729	2004	World Health Statistics 2010
Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	344	2004	World Health Statistics 2010
Age-standardized mortality rate by cancer (/100,000 population)	129	2004	World Health Statistics 2010
Mortality rate for tuberculosis (/100,000 population)	19	2008	World Health Statistics 2010
Mortality rate for Malaria (/100,000 population)	74	2006	World Health Statistics 2010

Section 2 Health Services

Indicator	Value	Year	Reference/Source
2.01 Health Expenditures Core Questions			
Total annual expenditure on health (millions US$ average exchange rate)	1,502	2008	Calculated from the National Health Accounts
Total annual expenditure on health (millions NCU)	107,498	2008	National Health Accounts
Total health expenditure as % of Gross Domestic Product	4.5	2008	National Health Accounts
Total annual expenditure on health per capita (US$ average exchange rate)	40	2008	National Health Accounts
Total annual expenditure on health per capita (NCU)	2,864	2008	Calculated from the NHA
General government annual expenditure on health (millions US$ average exchange rate)	563	2008	Calculated from the NHA
General government annual expenditure on health (millions NCU)	40,223	2008	National Health Accounts
Government annual expenditure on health as percentage of total government budget (% of total government budget)	7.1	2008	National Health Accounts
Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	37.4	2008	National Health Accounts
Annual per capita government expenditure on health (US$ average exchange rate)	15	2008	National Health Accounts
Annual per capita government expenditure on health (NCU)	1,072	2008	Calculated from the NHA
Private health expenditure as % of total health expenditure (% of total expenditure on health)	62.6	2008	National Health Accounts
Population covered by a public health service or public health insurance or social insurance, or other sickness funds (% of total population)	22%	2010	NHIF
Population covered by private health insurance (% of total population)	0.9%	2010	NHIF

Total pharmaceutical expenditure (millions US$ current exchange rate)	372	2006	Calculated from the NHA
Total pharmaceutical expenditure (millions NCU)	26,796	2006	National Health Accounts
Total pharmaceutical expenditure per capita (US$ current exchange rate)	9.9	2006	Calculated from the NHA
Total pharmaceutical expenditure per capita (NCU)	714	2006	Calculated from the NHA
Pharmaceutical expenditure as a % of GDP (% of GDP)	1.65	2006	Calculated from the NHA
Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	36.64	2006	National Health Accounts
Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	33.56	2006	Calculated from the NHA
Total public expenditure on pharmaceuticals (millions NCU)	2,420	2006	National Health Accounts
Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	9.03	2006	Calculated from the NHA
Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	0.92	2006	Calculated from the NHA
Total public expenditure on pharmaceuticals per capita (NCU)	66.19	2006	Calculated from the NHA
Total private expenditure on pharmaceuticals (million US$ current exchange rate)	143	2006	Calculated from the NHA
Total private expenditure on pharmaceuticals (millions NCU)	10,340	2006	National Health Accounts
Supplementary Questions			
Social security expenditure as % of government expenditure on health (% of government expenditure on health)	9.1	2008	National Health Accounts
Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	77.3	2008	National Health Accounts
Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	8.8	2008	National Health Accounts
2.02 Health Personnel and Infrastructure **Core Questions**			
Total number of pharmacists	1,773	2004	Global Health Atlas

licensed/registered to practice in your country			
Total number of pharmacists working in the public sector	600	2010	MOMS
Total number of pharmaceutical technicians and assistants	1,321	2004	Global Health Atlas
A strategic plan for pharmaceutical human resource development is in place in your country?	No		
Total number of physicians	4,506	2002	WHS 2010
Total number of nursing and midwifery personnel	37,113	2002	WHS 2010
Total number of hospitals	446	2008	HIS. July 2009
Total number of hospitals bed	49,523	2008	HIS. July 2009
Total number of primary health care units and centres	3,835	2008	HIS. July 2009
Supplementary Questions			
Starting annual salary for a newly registered pharmacist in the public sector - NCU	368,904	2010	MOMS
Total number of pharmacists who graduated (first degree) in the past 2 years in your country	107	2007	University of Nairobi
Are there accreditation requirements for pharmacy schools?	Yes		
Comments	The starting annual salary quoted is exclusive of allowances such as housing, medical, risk and non-practice allowance.		

Section 3 Policy issues

Indicator	Value	Year	Reference/Source
3.01 Policy Framework **Core Questions**			
National Health Policy exists. If yes, please write year of the most recent document in the "year" field and attach document or provide URL below*	Yes	1994	Kenya Health Policy Framework, 1994
National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field and attach document or provide URL below*	Yes	2010	Department of Pharmacy
Group of policies addressing pharmaceuticals exist. Please attach document or provide URL below *	No		
National Medicines Policy covers the following components:			
Selection of Essential Medicines	Yes		
Medicines Financing	Yes		
Medicines Pricing	Yes		
Medicines Procurement	Yes		
Medicines Distribution	Yes		
Medicines Regulation	Yes		
Pharmacovigilance	Yes		
Rational Use of Medicines	Yes		
Human Resource Development	Yes		
Research	Yes		
Monitoring and Evaluation	Yes		
Traditional Medicine	Yes		
National medicines policy implementation plan exists. If yes, please write year of the most recent document in the "year" field and attach document or provide URL below*	Yes	2010	Pharmaceutical Strategy, 2010-2015
Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes	1994	Public Health Act
There are official written guidelines on medicines donations.	Yes	2001	MoH

Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes	2010	National Annual Operational Plans & M&E Reports
Who is responsible for pharmaceutical policy monitoring?	Department of Pharmacy, Division of Pharmaceutical Policies		
Is there a national good governance policy?	Yes	2010	GJLOS - http://www.justice.go.ke
Multisectoral	Yes		
For the pharmaceutical sector	Yes	2010	KNPP
Which agencies are responsible?	Ministry of Justice, National Cohesion and Constitutional Affairs coordinates the GJLOS - a sector-wide - institutional reform program supported by more than 15 Development Partners.		
A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	No		
There is a formal code of conduct for public officials.	Yes	2006	Government of Kenya
Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsman)?	Yes	2010	Public Complaints Standing Committee of Kenya: www.justice.go.ke
Please describe:	Monitoring of pharmaceutical policy implementation is done within the context of the national joint health sector planning and M&E		
Comments	The Kenya National Pharmaceutical Policy 2010 is in the final stages of completion.		
3.02 Intellectual Property Laws and Medicines **Core Questions**			
Country is a member of the World Trade Organization	Yes	2010	Since 1995, WTO
Legal provisions provide for granting of Patents on pharmaceuticals	Yes	2010	Intellectual Property Act, 2001
National Legislation has been modified to implement the TRIPS Agreement	Yes	2010	Intellectual Property Act, 2001
Current laws contain (TRIPS) flexibilities and safeguards	Yes	2010	Intellectual Property Act, 2001
Country is eligible for the transitional period to 2016	No		
Which of the following (TRIPS) flexibilities			

and safeguards are present in the national law?			
Compulsory licensing provisions that can be applied for reasons of public health	Yes	2010	Intellectual Property Act, 2001
Bolar exception	Yes	2010	Intellectual Property Act, 2001
Are parallel importing provisions present in the national law?	Yes	2010	Intellectual Property Act, 2001
The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes	2010	Through the GSPOA
Are there legal provisions for data exclusivity for pharmaceuticals	Yes	2010	Intellectual Property Act, 2001
Legal provisions exist for patent extension	No	2010	Intellectual Property Act, 2001
Legal provisions exist for linkage between patent status and marketing authorization	No	2010	Intellectual Property Act, 2001
3.03 Manufacturing **Core Questions**			
Number of licensed pharmaceutical manufacturers in the country	45	2010	PPB
Country has manufacturing capacity for:		2010	PPB
R&D to discover new active substances	No		
Production of pharmaceutical starting materials (APIs)	No		
Production of formulations from pharmaceutical starting material	Yes		
Repackaging of finished dosage forms	Yes		
Percentage of market share by value produced by domestic manufacturers (%)	28	2010	KNPP
Supplementary Questions			
Number of multinational pharmaceutical companies manufacturing medicines locally	0		
Number of manufacturers that are GMP certified	26	2010	PPB

Section 4 Regulation

Indicator	Value	Year	Reference/Source
4.01 Regulatory Framework			
Core Questions			
Are there legal provisions establishing the powers and responsibilities of the medicines regulatory authority?	Yes	2007	Cap 244
Part of MOH	Yes		
Semi autonomous agency	No		
The MRA has its own website	Yes	2010	PPB
- If yes, please provide MRA Web site address (URL)	www.pharmacyboardkenya.org		
The MRA is involved in harmonization/ collaboration initiatives	Yes	2010	PPB
- If yes, please specify	African Medicines Regulatory Harmonization; and Harmonization of Medicines Registration in the EAC		
An assessment of the medicines regulatory system has been conducted in the last five years.	Yes	2006	
Supplementary Questions			
Formal code of conduct exists for staff involved in medicines regulation	Yes	2006	GOK, CoR
Medicines Regulatory Authority gets funds from regular budget of the government.	No		
Medicines Regulatory Authority is funded from fees for services provided.	Yes	2010	PPB
Medicines Regulatory Authority receives funds/support from other sources	Yes	2010	PPB
Revenues derived from regulatory activities are kept with the regulatory authority	Yes	2010	PPB
The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes	2010	PPB
Comments	No direct funds from Government for the MRA but Technical Staff are seconded by the Government.		

	The computerized system is not adequate but the MRA is in the process of procuring an ERP.		
4.02 Marketing Authorization (Registration) **Core Questions**			
Legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market	Yes	2010	PPB
Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products	Yes	2010	PPB
Number of pharmaceutical products registered in your country	13,000	2010	PPB
Legal provisions require the MRA to make publicly available the registered pharmaceutical with defined periodicity	No	2010	PPB
Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN	Yes	2010	PPB
Legal provisions require paying a fee for Medicines Market Authorization (registration) applications	Yes	2010	PPB
Supplementary Questions			
Legal provisions require marketing authorization holders to provide information about variations to the existing marketing authorization	Yes	2010	PPB
Legal provisions require to publish the Summary Product Characteristics (SPCs) of the medicines registered	Yes	2010	PPB
Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes	2010	PPB
Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the marketing authorization application	Yes	2010	PPB
Legal provision require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes	2010	PPB
Legal provisions allow applicants to appeal against MRAs decisions	Yes	2010	PPB

Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity,NCE (US$)	1000	2010	PPB
Registration fee - the Amount per application for a multisource pharmaceutical product (US$)	1000	2010	PPB
Time limit for the assessment of a marketing authorization application (Months)	6	2010	PPB
4.03 Regulatory Inspection **Core Questions**			
Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes	1957	Cap 244, Laws of Kenya
Does the Regulatory Authority have inspectors?	Yes	2010	PPB
If yes, how many?	43		
Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes	2010	PPB
Legal provisions exist requiring inspection to be performed	Yes	2010	PPB
Inspection is a pre-requisite for licensing of facilities	Yes	2010	PPB
Inspection requirements are the same for public and private facilities	Yes	2010	PPB
4.04 Import Control **Core Questions**			
Legal provisions exist requiring authorization to import medicines	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist allowing the sampling of imported products for testing	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized port of entry	Yes	1957	Cap 244, Laws of Kenya
4.05 Licensing **Core Questions**			
Legal provisions exist requiring manufacturers to be licensed If yes	Yes	2010	PPB

please provide documents below. Please attach document or provide URL below *			
Legal provisions exist requiring manufacturers to comply with Good manufacturing Practices (GMP)	Yes	2010	PPB
GMP requirements are published by the government. If yes, please provide reference or URL below *	Yes		
Legal provisions exist requiring importers to be licensed	Yes	2010	PPB
Legal provisions exist requiring wholesalers and distributors to be licensed	Yes	2010	PPB
Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices	Yes	2010	PPB
National Good Distribution Practice requirements are published by the government	Yes	2006	PPB
Legal provisions exist requiring pharmacists to be registered	Yes	2010	PPB
Legal provisions exists requiring private pharmacies to be licensed	Yes	2010	PPB
Legal provision exist requiring public pharmacies to be licensed	No	2010	PPB
National Good Pharmacy Practice Guidelines are published by the government	No	2010	PPB
4.06 Market Control and Quality Control **Core Questions**			
Legal Provisions for controlling the pharmaceutical market exist	Yes	2010	PPB
Does a laboratory exist in the country for Quality Control testing?	Yes	2010	PPB
Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes	2010	PPB
4.07 Medicines Advertising and Promotion **Core Questions**			
Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes	2010	PPB
Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Government		

Legal provisions prohibit direct advertising of prescription medicines to the public	Yes	2010	PPB
Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes	2010	PPB
Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes	2010	PPB
A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes	2010	PPB
If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both	Yes	2010	PPB
If yes, adherence to the code is voluntary	No	2010	PPB
If yes, the code contains a formal process for complaints and sanctions	Yes	2010	PPB
4.08 Clinical trials **Core Questions**			
Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes	1957	Cap 244, Laws of Kenya
Comments	National Clinical Trials Registry is currently under development by the Pharmacy and Poisons Board which is the medicines regulatory authority (MRA) in Kenya.		
Supplementary Questions			
Legal provisions exist for GMP compliance of investigational products	No		
Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes		
Legal provisions permit inspection of facilities where clinical trials are	Yes		

performed			
Comments	New Guidelines for Conducting Clinical Research in Kenya are being developed by the PPB. It is in its final stages of completion.		
4.09 Controlled Medicines **Core Questions**			
The country is a signatory to conventions			
Single Convention on Narcotic Drugs, 1961	Yes	2009	International Narcotics Control Board
The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes	2009	International Narcotics Control Board
Convention on Psychotropic Substances 1971	Yes	2009	International Narcotics Control Board
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes	2009	International Narcotics Control Board
Laws for the control of narcotic and psychotropic substances, and precursors exist, If yes, please attach below *	No	2007	WHO Level I
Annual consumption of Morphine (mg/capita)	0.575	2007	WHO Level I
Supplementary Questions			
Annual consumption of Fentanyl (mg/capita)	0.000074	2007	International Narcotics Control Board
Annual consumption of Pethidine (mg/capita)	1.215	2007	International Narcotics Control Board
4.10 Pharmacovigilance **Core Questions**			
There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes	1957	Cap 244, Laws of Kenya
Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes	1957	Cap 244, Laws of Kenya
Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes	1957	Guidelines for National PV System in Kenya
A national Pharmacovigilance centre linked to the MRA exists in your country	Yes	2009	Guidelines for National PV System in Kenya
If a national pharmacovigilance centre	3	2010	PPB

exists in your country, how many staff does it employ full-time			
If a national pharmacovigilance center exists in your country, an analysis report has been published in the previous two years. Please attach document or provide URL below *	No		
If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	No		
An official standardized form for reporting ADRs is used in your country. If yes, please attach document below *	Yes	2009	Suspected ADR Reporting Form (Yellow Form)
A national Adverse Drug Reactions database exists in your country.	Yes	20010	Based on Vigiflow
Are ADR reports set to the WHO database in Uppsala?	Yes	2010	Vigiflow
If yes, number of reports sent in the past two years	23	2010	
ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes	2009	Malaria and HIV/AIDS
Comments	Legal provisions are provided for in Chapter 244. National Guidelines are available. PPB does not publish bulletins yet, but departmental reports and post-market surveillance reports are available.		
Supplementary Questions			
How many ADR reports are in the database?	23	2010	Vigibase
How many reports have been submitted in the past two years?	23	2010	Vigibase
Feedback is provided to reporters	Yes	2009	PPB
The ADR database is computerized	Yes	2010	Vigibase
Medications errors (MEs) are reported.	Yes		
How many MEs are there in the ADRs database?	0		
There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes	2010	Guidelines for Drug Registration in Kenya 2010
In the past two years, who has reported ADRs?		2009	PPB

Doctors	Yes		
Nurses	Yes		
Pharmacists	Yes		
Consumers	No		
Pharmaceutical Companies	Yes		
Was there any regulatory decision based on local PV data in the last 2 years?	No		
Are there training courses in Pharmacovigilance?	Yes	2009	PV Training Currculum and Implementation Guide and Manuals
If yes, how many people have been trained in the past two years?	350	2009	PPB
Comments	The Pharmacovigilance system was formally launched in 2009 and scale-up is ongoing. Access to Vigibase is provided in May 2010. ADR Database does not capture ME reports which are captured differently.		

Section 5 Medicines Financing

Indicator	Value	Year	Reference/Source
5.01 Medicines Coverage and Exemptions Core Questions			
If a public programme providing free medicines exists, medicines are available free-of-charge for:			
Patients who cannot afford them	Yes	2010	
Children under 5	Yes	2010	
Pregnant women	Yes	2010	
Elderly persons	Yes	2010	
If a public programme providing some/all medicines free exists, the following types of medicines are free			
All medicines for all conditions	No		
Any non-communicable diseases	No		
Malaria medicines	Yes	2010	National Malaria Program
Tuberculosis medicines	Yes	2010	National TB Program
Sexually transmitted diseases medicines	Yes	2010	National AIDS and STI Program
HIV/AIDS medicines	Yes	2010	National AIDS and STI Program
EPI vaccines	Yes	2010	National Immunization Program
If others, please specify	Reproductive Health Commodities		
Does a public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage	Yes		
Does it provide coverage for medicines that are on the EML for inpatients	No		
Does it provide coverage for medicines that are on the EML for outpatients	No		
Does it provide at least partial medicines coverage for inpatients	Yes		
Does it provide at least partial medicines coverage for outpatients	No		
Please describe/explain your answers for questions above	National Health Insurance Fund currently provides in-patient cover for 'lodging' costs only. An outpatient program has been initiated on a pilot basis.		

Do private health insurance schemes provide any medicines coverage?	Yes	2008	WHO/HAI Survey
If yes, is it required to provide at least partial coverage for medicines that are on the EML?	Unknown		
Comments	Private insurance coverage is not currently linked to the EML		
5.02 Patients Fees and Copayments **Core Questions**			
In your health system, at the point of delivery, are there any copayment/fee requirements for consultations	Yes	2010	
In your health system, at the point of delivery, are there any copayment/fee requirements for medicines	Yes	2010	
Is revenue from fees or from the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility	No	2010	
Please describe the patient fees and copayments system	For primary care facilities level 1&2, patients pay a fee of KES 10 & 20 respectively. There are no guidelines for copayments at other levels. Revenue is mostly used for facility operating costs.		
5.03 Pricing Regulation for the Private Sector **Core Questions**			
Are there legal or regulatory provisions affecting pricing of medicines	No	2010	PPB
Government runs an active national medicines price monitoring system for retail prices	Yes	2010	MoH/WHO/HAI - Monitoring Medicine Prices & Availability
Regulations exists mandating that retail medicine price information should be publicly accessible	No		
5.04 Prices, Availability and Affordability **Core Questions**			
Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country.	Yes		
Basket of key medicines	Public procurement	Public patient	Private patient

Availability (one or both of)	Mean (%)	**Orig.**		66	81
		LPG		NA	NA
	Median (%)	**Orig.**		NA	55
		LPG		NA	72.4
Price	Median Price Ratio	**Orig.**	NA	3.6	18.1
		LPG	0.65	1.99	3.33
Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	Number of days' wages	**Orig.**		NA	1.5
		LPG		0.2	0.2

5.05 Price Components and Affordability **Core Questions**			
Please state if a survey of medicines price components has been conducted in the past 5 years in your country. If yes, please indicate the year of the survey and use the results to fill in the questions below	Yes	2007	MoH/HAI/WHO
Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the public sector (Median % contribution)	-		
Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)	-		
5.06 Duties and Taxes on Pharmaceuticals (Market) **Core Questions**			
There are duties on imported active pharmaceutical ingredients (APIs)	No		
There are duties on imported finished	No		

products			
VAT (value-added tax) or any other tax on pharmaceuticals	Yes		
Comments	Import Declaration Fees (IDF) are levied, and amount to indirect tax on pharmaceuticals. Duty and VAT are applicable to some packaging materials for pharmaceuticals, which affects the final price.		
Supplementary Questions			
Amount of duties on imported active pharmaceutical ingredients, APIs (%)	0		
Amount of duties on imported finished products (%)	0		
Amount of VAT on pharmaceutical products (%)	0		

Section 6 Pharmaceutical procurement and distribution

Indicator	Value	Year	Reference/Source
6.01 Public Sector Procurement Core Questions			
Public sector procurement is			
Decentralized	No		
Centralized and decentralized	Yes		
If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:			
Part of MoH	No		
Semi-Autonomous	Yes		
Autonomous	No		
A government procurement Agency which procures all public goods	Yes		
Public sector tenders bids documents are publicly available	No		
Public sector awards are publicly available	Yes		
Procurements are based on prequalification of suppliers	Yes		
If yes, please describe how it works	Pre-qualification is only carried out where items are procured by Quotation.		
Comments	Public sector bid documents are available only to bidders who purchase the bid documents		
Supplementary Questions			
Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field.	Yes	2005	PPDA
Are there provisions giving priority in public procurement to goods produced by local manufacturers?	Yes	2005	PPDA
The key functions of the procurement unit and those of the tender committee are clearly separated	Yes	2007	WHO Level I
A process exists to ensure the quality of products procured	Yes		
If yes, the quality assurance process includes pre-qualification of products and suppliers	No		

If yes, explicit criteria and procedures exist for pre-qualification of suppliers	No		
If yes, a list of pre-qualified suppliers and products is publicly available	No		
List of samples tested during the procurement process and results of quality testing is available	No		
Which of the following tender methods are used in public sector procurement:		2005	PPDA
National competitive tenders	Yes		
International competitive tenders	Yes		
Direct purchasing	Yes		
Comments	Post-qualification of bids is a step-wise procedure involving examination of documents and evaluation of organoleptic properties of the commodities.		
6.02 Public Sector Distribution **Core Indicators**			
The government supply system department has a Central Medical Store at National Level	Yes	2010	
Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	8	2010	KEMSA
There are national guidelines on Good Distribution Practices (GDP)	Yes	2006	Guidelines for Good Distribution Practice 2006
There is a licensing authority that issues GDP licenses	No		
List of GDP certified warehouses in the public sector exists	No		
List of GDP certified distributors in the public sector exists	No		
Supplementary Questions			
Which of the following processes at the Central Medical Store is in place			
Forecasting of order quantities	No		
Requisition/Stock orders	No		
Preparation of picking/packing slips	Yes		
Reports of stock on hand	Yes		
Reports of outstanding order lines	No		
Expiry dates management	Yes		
Batch tracking	Yes		
Reports of products out of stock	Yes		

Percentage of selected medicines with at least one stock out in the past year (%)			
Routine Procedure exists to track the expiry dates of medicines	Yes		
The Public Central Medical Store is GDP certified by a licensing authority	No		
The Public Central Medical Store is ISO certified	Yes	2010	Bureau Veritas
The second tier public warehouses are GDP certified by a licensing authority	No		
The second tier public warehouses are ISO certified	No		
6.03 Private Sector Distribution **Core Questions**			
Legal provisions exist for licensing wholesalers in the private sector	Yes		
Legal provisions exist for licensing distributors in the private sector	Yes		
List of GDP certified wholesalers in the private sector exists	No		
List of GDP certified distributors in the private sector exists	No		

Section 7 Selection and Rational Use

Indicator	Value	Year	Reference/Source
7.01 National Structures **Core Questions**			
National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes	2009	MOMS and MOPHS
If yes, STG's are applied to Primary care. Please use the "year" field to write the year of last update of primary care STGs.	Yes	2009	MOMS and MOPHS
If yes, STG's are applied to Secondary (hospitals). Please use the "year" field to write the year of last update of secondary care STGs.	Yes	2009	MOMS and MOPHS
If yes, STG's are applied to Paediatric conditions. Please use the "year" field to write the year of last update of paediatric condition STGs.	Yes	2009	MOMS and MOPHS
National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field and attach document or provide URL below.	Yes	2010	MOMS and MOPHS
If yes, number of medicines on the EML	359		
If yes, there is a written process for selecting medicines on the EML	Yes		
If yes, the EML is publicly available	Yes		
% of public health facilities with copy of EML (mean)- Survey data	42	2008	WHO Level II
% of public health facilities with copy of STGs (mean)- Survey data	39	2008	WHO Level II
A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes	2010	PPB
Public education campaigns on rational medicine use topics have been conducted in the previous two years	No		
A survey on rational use of medicines has been conducted in the previous two years	Yes	2008	WHO/HAI Level II

A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes	2010	Guidelines for Appropriate Medicines Use, 2010
A written National Strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field and attach document or provide URL below.	No		
Supplementary Questions			
The EML includes formulations specific for children	Yes		
There are explicit documented criteria for selection of medicines in the EML	Yes		
There is a formal committee or other equivalent structure for the selection of products on the national EML	Yes	2007	NMTC
If yes, provide the official documentation establishing the committee *	ToRs for the NMTC		
National medicines formulary exists	No		
Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	No		
A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes	2010	KEMRI
Comments	The Kenya Medical Research Institute (KEMRI) does the work on antimicrobial resistance.		
7.02 Prescribing **Core Questions**			
Legal provisions exist to govern the licensing and prescribing practices of prescribers	Yes		Medical Practioners and Dentists Act
Legal provisions exist to restrict dispensing by prescribers	Yes		
Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes		
The core medical training curriculum includes components on:			
Concept of EML	-		
Use fo STGs	-		

Pharmacovigilance	-		
Problem based pharmacotherapy	-		
The core nursing training curriculum includes components on:			
Concept of EML	-		
Use of STGs	-		
Pharmacovigilance	-		
The core training curriculum for paramedical staff includes components on:			
Concept of EML	-		
Use of STGs	-		
Pharmacovigilance	-		
Mandatory continuing education that includes pharmaceutical issues is required for Doctors	Unknown		
Mandatory continuing education that includes pharmaceutical issues is required for Nurses	Unknown		
Mandatory continuing education that includes pharmaceutical issues is required for Paramedical staff	Unknown		
Prescribing by INN name is obligatory in:			
Private sector	No		
Public sector	No		
Average number of medicines prescribed per patient contact in public health facilities (mean)	3	2008	WHO/HAI Level II Survey
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	93.4	2008	WHO/HAI Level II Survey
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	31.8	2008	WHO/HAI Level II Survey
% of patients in outpatient public health care facilities receiving antibiotics (mean)	76.7	2008	WHO/HAI Level II Survey
% of patients in outpatient public health care facilities receiving injections (mean)	13.3	2008	WHO/HAI Level II Survey
% of prescribed drugs dispensed to patients (mean)	86	2008	WHO/HAI Level II Survey
% of medicines adequately labeled in public health facilities (mean)	5	2008	WHO/HAI Level II Survey
Supplementary Questions			
A professional association code of	Yes		

conduct exists governing professional conduct of doctors			
A professional association code of conduct exists governing professional conduct of nurses	Yes		
Diarrhoea in children treated with ORS (%)	80	2008	WHO/HAI Level II Survey
7.03 Dispensing **Core Questions**			
Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes	2010	PPB
The basic pharmacist training curriculum includes components on:		2010	PPB
Concept of EML	Yes		
Use of STGs	Yes		
Drug Information	Yes		
Clinical pharmacology	Yes		
Medicines supply management	Yes		
Mandatory continuing education tat includes rational use of medicines is required for pharmacists	No	2010	PPB
Substitution of generic equivalents at the point of dispensing in public sector facilities is allowed	Yes	2010	PPB
Substitution of generic equivalents at the point of dispensing in private sector facilities is allowed	Yes	2010	PPB
Antibiotics are sold over-the-counter without a prescription	Yes	2008	WHO/HAI Level II
Injectable medicines are sold over-the-counter without a prescription	Yes	2008	WHO/HAI Level II
Supplementary Questions			
A professional association code of conduct exists governing professional behaviour of pharmacists	Yes	2010	PSK
Are the following categories of staff prescribing prescription-only medicines at primary care level in the public sector?		2010	MoH
Doctors	No		
Nurses	Yes		
Pharmacists	No		

Section 8 Household data/access

Indicator	Value	Year	Reference/Source
8.01 Data from Household Surveys **Core Questions**			
What household surveys have been undertaken in the past 5 years to assess access to medicines?	WHO/HAI Household Survey		
Adults with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	89.0	2008	WHO/HAI HH Survey
Adults with acute conditions not taking all medicines because they cannot afford them (%)	32.1	2003	World Health Survey
Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	82.1	2003	World Health Survey
Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)	47.4	2003	World Health Survey
Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)	87.0	2008	WHO/HAI HH Survey
Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)	100.0	2003	World Health Survey
Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)	88.9	2003	World Health Survey
Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	85.8	2003	World Health Survey
Supplementary Questions			
Adults with acute conditions not taking all medicines because the medicines were not available (%)	68.8	2003	World Health Survey
Adults with chronic conditions not taking all medicines because they cannot afford them (%)	50.2	2003	World Health Survey
Adults with chronic conditions not taking	49.8	2003	World Health Survey

all medicines because the medicines were not available (%)			
Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)	86.7	2003	World Health Survey
Children with acute conditions not taking all medicines because they cannot afford them (%)	22.7	2003	World Health Survey
Children with acute conditions not taking all medicines because the medicines were not available (%)	71.3	2003	World Health Survey
Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)	29.2	2003	World Health Survey
Comments	Some of these indicators were not computed for the latest HH survey. Therefore figures given are for 2003.		

[i] World Health Organisation (WHO) (2010), "World Health Statistics 2010", WHO Press, Geneva. Available online: http://www.who.int/whosis/whostat/2010/en/index.html.